510(k) Summary

as required by section 807.92(c).

P-TLIF

K130506

Institute of Musculoskeletal Science & Education

90 S. Newtown Street Rd., Suite #10

Newtown Square, PA 19073

John Moran

CEO

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Submitted 4/4/13

MAY 1 3 2013

Submitter:	Institute of Musculoskeletal Science & Education 90 S. Newtown Street Rd., Suite #10 Newtown Square, PA 19073
Contact Person	John Moran CEO Phone: (484) 420-4219 Email: mberwyn@aol.com

Trade Name	IMSE P-TLIF
Common Name	P-TLIF
Device Class	Class II
Classification Name and Number	Intervertebral Fusion Device With Bone Graft, Lumbar 21 CFR 888.3080
Classification Panel:	Orthopedic
Product Code	MAX
Reason for 510k	New Device
Predicate Devices	Camber Cage (K121254), Corelink Foundation Cage (K 073440), Stryker AVS PL (K093704) & K2M Aleutian (K113138)
Device Description	Institute of Musculoskeletal Science and Education, P-TLIF is a device for interbody fusion of the anterior column of the spine. These cages are hollow so that bone can grow through the device, fusing the adjacent bony surfaces. IMSE, P-TLIF is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths, heights and shapes. Institute of Musculoskeletal Science and Education designed the IMSE, P-TLIF to be placed through a transforaminal or posterior approach and to address vertebrae in the lumbosacral region of the spine.

Intended Use	The IMSE P-TLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). IMSEP-TLIF is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach. IMSEP-TLIF implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Materials:	The implant is manufactured from ASTM2026 Solvay Zeniva ZA-500 implant grade Polyetheretherketone (PEEK)

Statement of Technological Comparison	IMSE, P-TLIF and its predicate devices have the same indications for use, similar design, and test results. Both devices are manufactured using materials with a long history of use in orthopaedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the IMSEP-TLIF is substantially equivalent to other predicate devices. • Static and Dynamic Compression Test per ASTM F2077 • Static and Dynamic Compression Shear ASTM F2077 • Subsidence Test per ASTM F2267 • Wear Debris ASTM F2077 and ASTM F1877 • Static Expulsion Test The results of these studies showed that the IMSEP-TLIF met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Sterilization Information	
Implants	The implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.
Instruments and Case	The instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.

Conclusion	The IMSE, P-TLIF is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Lumbar Cage and its predicate devices have the same indications for use, have a similar design and technical characteristics, similar test results, and any differences do not raise question of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Institute of Musculoskeletal Science & Education
% Mr. John Moran
CEO
90 South Newtown Street Road, Suite #10
Newtown Square, Pennsylvania 19073

Letter dated: May 13, 2013

Re: K130506
Trade/Device Name: IMSE P-TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Codes: MAX
Dated: April 5, 2013
Received: April 5, 2013

Dear Mr. Moran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130506

Device Name: IMSE P-TLIF

Indications:

The Institute of Musculoskeletal Science & Education P-TLIF is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Institute of Musculoskeletal Science & Education P-TLIF is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

Institute of Musculoskeletal Science & Education P-TLIF implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X **AND/OR** **Over-the-counter** _____

(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices